TENNESSEE GENERAL ASSEMBLY
FISCAL REVIEW COMMITTEE

FISCAL MEMORANDUM

HB 572 - SB 984

March 21, 2015

SUMMARY OF ORIGINAL BILL: Requires a prescriber to allow for a substitution of a prescribed biological product (biologic) for an interchangeable biologic product (biosimilar) unless the prescriber determines that the medical necessity of a biologic is preferable over the biosimilar or an equivalent biosimilar is not available. Establishes guidelines governing which instances allow for the substitution of a biologic for a biosimilar. Sets the definition of a "biological product" or biologic equal to the definition subscribed to in federal statute. Defines "interchangeable biological product" or biosimilar as a biologic licensed by the federal Food and Drug Administration (FDA) and determined to meet the federal safety standards for determining interchangeability or a biologic determined by the FDA to be therapeutically equivalent as set forth in the latest edition or supplement of the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations."

A pharmacist which makes the substitution of a biologic for a biosimilar is required to denote the substitution on the prescription label. A pharmacist is required to notify the prescriber of any dispensed biologic unless no FDA-approved biosimilar exists for the prescribed biologic or a refill prescription does not change the product dispensed from the prior filling of the prescription. A pharmacist must maintain a record of all dispensed biologics.

Requires any manufacturer, packager, or distributor of any human use legend drug or biologic sold, delivered, or offered for sale in this state to print the name and address of the manufacturer, packager, or distributor of the finished dosage form on the label of the immediate container of the biologic.

This legislation does not apply to prescriptions dispensed for inpatients at a hospital, a nursing home, or an assisted-care living facility. Notification requirements provided in this legislation do not apply to vaccines. Requires the Board of Pharmacy to maintain a link on its web site to the current list of all biologics determined by the FDA to be biosimilars.

FISCAL IMPACT OF ORIGINAL BILL:

Increase State Expenditures – Not Significant/Board of Pharmacy

Other Fiscal Impact - Authorizing physicians to substitute biosimilars for biologics is expected to result in a decrease in health care costs. Only one biosimilar is currently FDA-approved; therefore, any cost savings in the short-term is difficult to determine and is based on many factors, including the rate at which additional biosimilars become FDA-approved, the rate at which biosimilars are prescribed over biologics, and the actual cost difference between the biologic and equivalent biosimilar.

SUMMARY OF AMENDMENTS (004523, 004576, 004003, 003880): Deletes all language after the enacting clause. Requires a prescriber to allow for a substitution of a prescribed biological product (biologic) for an interchangeable biologic product (biosimilar) unless the prescriber determines that the medical necessity of a biologic is preferable over the biosimilar or an equivalent biosimilar is not available. Establishes guidelines governing which instances allow for the substitution of a biologic for a biosimilar. Sets the definition of a "biological product" or biologic equal to the definition subscribed to in federal statute. Defines "interchangeable biological product" or biosimilar as a biologic licensed by the federal Food and Drug Administration (FDA) and determined to meet the federal safety standards for determining interchangeability or a biologic determined by the FDA to be therapeutically equivalent as set forth in the latest edition or supplement of the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations."

A pharmacist which makes the substitution of a biologic for a biosimilar is required to denote the substitution on the prescription label. A pharmacist is required to notify the prescriber of any dispensed biologic unless no FDA-approved biosimilar exists for the prescribed biologic or a refill prescription does not change the product dispensed from the prior filling of the prescription. A pharmacist will only be required to communicate the biological product dispensed through an electronic medical records system when such a system is in place and the information is accessible to prescribers. A pharmacist must maintain a record of all dispensed biologics.

Requires any manufacturer, packager, or distributor of any human use legend drug or biologic sold, delivered, or offered for sale in this state to print the name and address of the manufacturer, packager, or distributor of the finished dosage form on the label of the immediate container of the biologic.

This legislation does not apply to prescriptions dispensed for inpatients at a hospital, a nursing home, or an assisted-care living facility. Notification requirements provided in this legislation do not apply to vaccines. Requires the Board of Pharmacy to maintain a link on its web site to the current list of all biologics determined by the FDA to be biosimilars. This legislation has an effective date of July 1, 2015.

FISCAL IMPACT OF BILL WITH PROPOSED AMENDMENTS:

Unchanged from the original fiscal note.

Assumptions for the bill as amended:

- A biologic can be a virus, therapeutic serum, vaccine, protein, blood component or other product used to prevent, treat, or cure a disease or condition in the human body.
- Biosimilars are highly similar to their equivalent biologics, but have minor differences in clinically inactive components; however, they remain similar in terms of therapeutic results.
- The Patient Protection and Affordable Care Act (PPACA) included the Biologics Price Competition and Innovation Act, which created a pathway for the FDA to begin

approval of biosimilars. The first FDA-approved biosimilar was Zarxio, and was approved on March 6, 2015. It is the only FDA-approved biosimilar; however, the FDA is expected to approve additional biosimilars in the future.

- Europe has approved and sold biosimilars since 2006. In the European market, biosimilars have proven to be the cheaper alternative to biologics. Biosimilars are expected to be a cheaper alternative to biologics in the U.S. drug market and will also provide greater competition, thereby, further driving down the cost of biologics and subsequently, health care costs in the U.S. Provided, only one biosimilar product is currently FDA-approved, it is difficult to predict any short-term cost savings experienced as a result of this legislation. Any such savings will be determined upon the rate at which additional biosimilars become FDA-approved, the rate at which biosimilars are prescribed over biologics, and the actual cost difference between the biologic and equivalent biosimilar product.
- The Board of Pharmacy can maintain a link on its website at no additional cost.
- Pursuant to Tenn. Code Ann. § 4-29-121, all health related boards are required to be self-supporting over a two-year period.
- The Board of Pharmacy had an annual surplus of $296,813 in FY12-13, an annual deficit of $66,136 in FY13-14, and a cumulative reserve balance of $1,160,083 on June 30, 2014.

CERTIFICATION:

The information contained herein is true and correct to the best of my knowledge.

Jeffrey L. Spalding, Executive Director

/jdb